

MR DUDLEYS TOPICAL CYCLE RELIEF WITH NUTMEG- menthol cream
Dudley Wellness Company Inc

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Drug Fact

Active Ingredient

Menthol 2.5%

Purpose

Temporary relief of minor arthritis pain, backache, muscle strains, sprains, and menstrual cramps.

Keep out of reach of children

Indications and Usage

Temporary relief of minor arthritis pain, backache, muscle strains, sprains, and menstrual cramps.

Apply generously and massage into the affected area until thoroughly absorbed into the skin, repeat as and when needed for pain but not more than 4 times a day.

Warnings

Keep out of reach of children.

For external use only, use only as directed.

Do not apply to wound or broken skin.

If redness present discontinue and consult a doctor.

Do not bandage tightly or use a heating pad.

If the condition persists for more than 5 days, discontinue use and consult a doctor.

Avoid contact with eyes and other mucous membranes.

If you are pregnant or nursing a baby, seek the advice of a healthcare professional before using this product.

Dosage and administration.

Apply generously and massage into the affected area until thoroughly absorbed into the skin, repeat as and when needed for pain but not more than 4 times a day.

Inactive ingredient.

Water

SD Alcohol

Glycerine

PEG-440 Hydrogenated Castor Oil

Methyl Salicylate

Caprylic Capric Triglyceride

Sodium Acrylate Copolymer

Eugenol

Methyl Eugenol

Nutmeg Oil

Methylisoeugenol

Methoxy Eugenol

Blue # 1

Principal Display panel

Mr. Dudley's

CYCLE RELIEF
CREAM

with NUTMEG



for women

- Fast Acting
- Deep Penetrating
- Menstrual Cramp Relief

4.5 oz.

DRUG FACTS

Active Ingredients: Menthol 2.5%...Topical analgesic

Uses: For the temporary relief of minor arthritis pain, backache, muscle strains and menstrual cramps.

Directions: Apply generously and massage into the affected area until thoroughly absorbed into the skin. Repeat as needed for pain, but not more than 4 times per day.

Warning: For external use only! Use only as directed! Do not apply to wounds or damaged skin. If redness is present, discontinue use and consult a doctor. Do not bandage tightly or use a heating pad. If the condition persists for more than 5 days, discontinue use and consult a doctor. Avoid contact with eyes and other mucous membranes. If you are pregnant or nursing a baby, seek the advice of a healthcare professional before using this product. Keep out of the reach of children.

Other Ingredients: Water, SD Alcohol, Glycerine, PEG-40 Hydrogenated Castor Oil, Methyl Salicylate, Caprylic Capric Triglyceride, Sodium Acrylate Copolymer, Eugenol, Methyl Eugenol, Nutmeg Oil, Methylisoeugenol, Methoxy Eugenol, & Blue #1.

Distributed by:

Dudley Wellness Co. Inc.
www.DudleyWellnessCompany.com
(800) 392-9231

Manufactured by:

Dudley Manufacturing LLC
7210 Cessna Drive
Greensboro, NC 27409



MR DUDLEYS TOPICAL CYCLE RELIEF WITH NUTMEG

menthol cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58484-200
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	2.5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
Methyl Salicylate (UNII: LAV5U5022Y)	
Water (UNII: 059QF0KO0R)	
ALCOHOL (UNII: 3K9958V90M)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
ACRYLAMIDE (UNII: 20R035KLCI)	
EUGENOL (UNII: 3T8H1794QW)	
METHYL EUGENOL (UNII: 29T9VA6R7M)	
NUTMEG OIL (UNII: Z1CLM48948)	
METHYL ISOEUGENOL (UNII: 46RN7Q97DE)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58484-200-45	128 g in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	10/24/2013	

Labeler - Dudley Wellness Company Inc (078816740)

Establishment

Name	Address	ID/FEI	Business Operations
Dudley Manufacturing LLC		830613076	manufacture(58484-200)

Revised: 10/2013

Dudley Wellness Company Inc